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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/011,167	10/05/1998	JOHANNES J. GEUZE	RILE.001.OOU	9536

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/011,167	Applicant(s) GEUZE ET AL.	
	Examiner Amy M. DeCloux	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): The objections and 112 second paragraph rejection..

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *13-17*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The 112 first paragraph rejections have been maintained, essentially for the reasons of record.

Applicant traverses the 112 first written description rejection on the grounds that Applicants have described generally in the specification that vesicles containing MHC Class I and/or II molecules can be obtained and have described that antigen presenting cells such as B cells can be used as a source of such vesicles, and r_fers to page 6, lines 1-6 of the specification. However, the Examnier notes that page 6, lines 1-6, of the specification mentions only MHC Class II, and does not mention MHC Class I. Therefore, as stated in the previous office actions, the examiner again notes that the instant specification describes an antigen presenting vesicle obtainable from a B cell wherein said vesicle comprises a MHC Class II protein, but does not describe that said vesicle (or any vesicle) from a B cell comprises MHC Class I protein. Applicant further asserts that it was known in the prior art that B lymphocytes express MHC CLass I molecules. However, the examiner notes that Applicant supplies no reference supporting said assertion, and does not state how the presence of MHC CLasss I expression in B cells relates to the instant claims drawn to an antigen presenting vesicle comprising MHC Class I protein. Applicant further contends that the specification describes that B lymphocytes secrete membrane vesicles that express MHC molecules. The examiner notes that the MHC molecules referred to are MHC Class II and not the instantly claimed MHC Class I molecules, as discussed supra. Applicant furthe contends that MHC molecules were internalized in vesicles that could be isolated. Again the examiner notes that the referenced MHC molecules are MHC Class II molecules, not the instantly claimed MHC Class I molecules. Applicant further contends that it "follows that vesicles obtained starting with a source of cells that express MHC Class I protein on their surface inherently will contain MHC Class I protein". However, the examiner notes that the arguments of counsel cannot take the place of objective evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). Further, the Examine rnotes that the legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession, at the time of invention, of the claimed antigen presenting vesicle obtainable from a B cell wherein said vesicle comprises a MHC Class I protein.

Applicant traverses the 112 first enablement rejection on the grounds that the general technical teaching of the specification is that the claimed vesicles contain Class I molecules. Applicant contends that the post filing date reference by Zitvogel confirms that the supernatant of B cells can be used to isloate vesicles comprising MHC Class I and Class II by differential ultracentrifugation and fractionation as disclosed in the specification, and that Zitvogel obtained similar sized vesicles as those disclosed in the instnat specification, and that accordingly undue experimentaion is not required. However, the examiner notes that a specification must be enabled at the time of filing. Further, it is not clear where the instant specification discloses that said isolated vesicles from B cells comprise MHC Class I molecules. Applicant further contends that western blot and immunoprecipitation analyses used to detect the presence of MHC Class I as well as MHC Class II molecules, can be carried out using techniques welll known to those in the art at the time of the filing of the application, and by following procedures disclosed in the specification on pages 3-4, 8-10 and 12-13. However, the Examiner notes that pages 3-4 and 8-10 disclose only MHC Class II not MHC Class I molecules, and that said pages 12-13 disclose no procedures. Applicant contends that by following the detailed exemplification provided in the specification for obtaining vesicles contaiing MHC Class II molecules, the claimed vesicles which compris MHC Class I molecules can be obtained without undue experimentation. However, the examiner notes that the arguments of counsel cannot take the place of objective evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). Applicant furhter contends that the Tse et al reference is not enabling because it only says that Class I MHC molecules are excluded from vesicles that ae internalized that contain class II MHC molecules, but does not say that B cells do not internalize MHC Class I molecules in vesicles. However, the examiner notes that this reference teaches that all vesicles that contain MHC Class II do not necessarily contain MHC Class I molecules, and therefore, substantiates the examiner's contention of record that it would require undue experimentation to predict which vesicles comprise MHC Class I molecules as claimed from B cells without further guidance from the specification. Applicant also contends that two post-filing date references teaches the presence of MHC Class I and II in human B cell derived membrane vesicles, wherein said vesicles were isolated using in essence the same procedures described in the specification. However the examiner notes that the specification must be enabling at the time the invention was filed.

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
5/9/03